The Department of Health and Human Services
And
The Department of Justice
Health Care Fraud and Abuse Control Program
Annual Report For FY 2004

SEPTEMBER 2005

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GENERAL NOTE
All years are fiscal years unless
otherwise noted in the text.

EXECUTIVE SUMMARY

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established a national Health Care Fraud and Abuse Control Program (HCFAC or the Program), under the joint direction of the Attorney General and the Secretary of the Department of Health and Human Services (HHS)[1], acting through the Department's Inspector General (HHS/OIG), designed to coordinate federal, state and local law enforcement activities with respect to health care fraud and abuse. In its eighth year of operation, the Program's continued success again confirmed the soundness of a collaborative approach to identify and prosecute the most egregious instances of health care fraud, to prevent future fraud or abuse, and to protect program beneficiaries.

Monetary Results

During 2004, the Federal Government won or negotiated approximately $605 million in judgments and settlements, and it attained additional administrative impositions in health care fraud cases and proceedings. The Medicare Trust Fund received transfers of more than $1.51 billion during this period as a result of these efforts, as well as those of preceding years, and an additional $99 million in federal Medicaid money was similarly transferred to the Centers for Medicare and Medicaid Services (CMS) as a result of these efforts. The HCFAC account has returned over $7.3 billion to the Medicare Trust Fund since the inception of the program in 1997.

Enforcement Actions

In FY 2004, U.S. Attorneys' Offices opened 1,002 new criminal health care fraud investigations involving 1,685 potential defendants. Federal prosecutors had 1,626 health care fraud criminal investigations pending, involving 2,361 potential defendants, and filed criminal charges in 395 cases involving 646 defendants. A total of 459 defendants were convicted for health care fraud-related crimes during the year. Also in FY 2004, the Department of Justice opened 868 new civil health care fraud investigations, and had 1,362 open civil health care fraud investigations. The Department of Justice filed complaints or intervened in 269 civil health care cases in 2004.

[1]Hereafter, referred to as the Secretary.

INTRODUCTION

ANNUAL REPORT OF
THE ATTORNEY GENERAL AND THE SECRETARY
DETAILING EXPENDITURES AND REVENUES
UNDER THE HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM
FOR FISCAL YEAR 2004

As Required by
Section 1817(k)(5) of the Social Security Act

STATUTORY BACKGROUND

The Social Security Act section 1128C(a), as established by the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191, HIPAA or the Act), created the Health Care Fraud and Abuse Control Program, a far-reaching program to combat fraud and abuse in health care, including both public and private health plans.

The Act requires that an amount equaling recoveries from health care investigations -- including criminal fines, forfeitures, civil settlements and judgments, and administrative penalties, but excluding restitution, compensation to the victim agency, and relators' shares -- be deposited in the Medicare Trust Fund.[2] All funds deposited in the Trust Fund as a result of the Act are available for the operations of the Trust Fund.

The Act appropriates monies from the Medicare Trust Fund to an expenditure account, called the Health Care Fraud and Abuse Control Account (the Account), in amounts that the Secretary and Attorney General jointly certify as necessary to finance anti-fraud activities. The maximum amounts available for certification are specified in the Act. Certain of these sums are to be used only for activities of HHS/OIG, with respect to Medicare and Medicaid programs. In 2004, the Secretary and the Attorney General certified $240.558 million for appropriation to the Account. A detailed breakdown of the allocation of these funds is set forth later in this report. These resources generally supplement the direct appropriations of HHS and the Department of Justice (DOJ) that are devoted to health care fraud enforcement, though they provide the sole source of funding for Medicare and Medicaid enforcement by HHS/OIG. (Separately, the Federal Bureau of Investigation (FBI) received $114 million from HIPAA which is discussed in the Appendix.)

[2]Also known as the Hospital Insurance (HI) Trust Fund. All further references to the Medicare Trust Fund refer to the HI Trust Fund.

Under the joint direction of the Attorney General and the Secretary, the Program's goals are:

(1) to coordinate federal, state and local law enforcement efforts relating to health care fraud and abuse with respect to health plans;

(2) to conduct investigations, audits, inspections, and evaluations relating to the delivery of and payment for health care in the United States;

(3) to facilitate enforcement of all applicable remedies for such fraud;

(4) to provide guidance to the health care industry regarding fraudulent practices; and

(5) to establish a national data bank to receive and report final adverse actions against health care providers, and suppliers.

The Act requires the Attorney General and the Secretary to submit a joint annual report to the Congress which identifies both:

(1) the amounts appropriated to the Trust Fund for the previous fiscal year under various categories and the source of such amounts; and

(2) the amounts appropriated from the Trust Fund for such year for use by the Attorney General and the Secretary and the justification for the expenditure of such amounts.

This annual report fulfills the above statutory requirements.

MONETARY RESULTS

As required by the Act, HHS and DOJ must detail in this Annual Report the amounts deposited and appropriated to the Medicare Trust Fund, and the source of such deposits. In 2004, $1.76 billion was deposited with the Department of the Treasury and the Centers for Medicare and Medicaid Services (CMS), transferred to other federal agencies administering health care programs, or paid to private persons during the fiscal year. The following chart provides a breakdown of the transfers/deposits:

Total Transfers/Deposits by Recipient FY 2004	
Department of the Treasury	
HIPAA Deposits to the Medicare Trust Fund	
Gifts and Bequests	47,358
Amount Equal to Criminal Fines	304,768,588
Civil Monetary Penalties	11,471,529
Asset Forfeiture *	0
Penalties and Multiple Damages	354,205,714
Centers for Medicare and Medicaid Services	
OIG Audit Disallowances - Recovered	141,350,000
Restitution/Compensatory Damages	802,659,281
Subtotal	**1,614,502,470**
Restitution/Compensatory Damages to Federal Agencies	
Office of Personnel Management	13,329,719
Veterans Administration	13,296,625
Administration for Children and Families	12,214,034
HHS/OIG Investigative Costs	7,308,459
TRICARE	5,533,522
Bureau of Primary Health Care	3,629,740
Other Agencies	3,645,279
Subtotal	**$58,957,378**
Relators' Payments**	**$82,867,287**
TOTAL ***	**$1,756,327,135**

*This includes only forfeitures under 18 U.S.C. § 1347, a Federal health care fraud offense that became effective on August 21, 1996. Not included are forfeitures obtained in numerous health care fraud cases prosecuted under Federal mail and wire fraud and other offenses.

**These are funds awarded to private persons who file suits on behalf of the Federal Government under the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b).

***Funds are also collected on behalf of state Medicaid programs and private insurance companies; these funds are not represented here.

The above transfers include certain collections, or amounts equal to certain collections, required by HIPAA to be deposited directly into the Medicare Trust Fund. These amounts include:

(1) Gifts and bequests made unconditionally to the Trust Fund, for the benefit of the Account or any activity financed through the Account;

(2) Criminal fines recovered in cases involving a Federal health care offense, including collections under section 24 (a) of title 18, United States Code (relating to health care fraud);

(3) Civil monetary penalties in cases involving a Federal health care offense;

(4) Amounts resulting from the forfeiture of property by reason of a Federal health care offense, including collections under section 982(a)(6) of title 18, United States Code; and

(5) Penalties and damages obtained and otherwise creditable to miscellaneous receipts of the general fund of the Treasury obtained under sections 3729 through 3733 title 31 of United States Code (known as the False Claims Act, or FCA), in cases involving claims related to the provision of health care items and services (other than funds awarded to a relator, for restitution or otherwise authorized by law).

PROGRAM ACCOMPLISHMENTS

EXPENDITURES

In the eighth year of operation, the Secretary and the Attorney General certified $240.558 million as necessary for the Program. The following chart gives the allocation by recipient:

FY 2004 ALLOCATION OF HCFAC APPROPRIATION
(Dollars in thousands)

Organization	Allocation
Department of Health and Human Services	
Office of Inspector General[3]	$160,000
Office of the General Counsel	4,667
Administration on Aging	3,276
Centers for Medicare and Medicaid Services	22,750
Health Resources and Services Administration (HRSA)	450
Subtotal	191,143
Department of Justice	
United States Attorneys	$30,400
Civil Division	14,459
Criminal Division	1,580
Civil Rights Division	1,976
Nursing Home Initiative	1,000
Subtotal	$49,415
Total	**$240,558**

[3]In addition, HHS/OIG obligated $1.71 million in funds received as "reimbursement for the costs of conducting investigations and audits and for monitoring compliance plans" as authorized by section 1128C(b) of the Social Security Act, 42 U.S.C. § 1320a-7c(b).

ACCOMPLISHMENTS

Overall Recoveries

During this fiscal year, the Federal Government won or negotiated approximately $605 million in judgments and settlements, and it attained additional administrative impositions in health care fraud cases and proceedings. The Medicare Trust Fund received transfers of more than $1.51 billion during this period as a result of these efforts, as well as those of preceding years, and an additional $99 million in federal Medicaid money was similarly transferred to CMS as a result of these efforts. Note that some of the judgments, settlements, and administrative actions that occurred in 2004 will result in transfers in future years, just as some of the transfers in 2004 are attributable to actions from prior years.

In addition to these enforcement actions, numerous audits, evaluations and other coordinated efforts yielded recoveries of overpaid funds, and prompted changes in Federal health care programs that reduce vulnerability to fraud. HHS agreed in FY 2004 to recover more than $601 million in OIG recommended refunds – the largest amount in the past 10 years.

Program Accomplishments

Working together, HHS/OIG, DOJ and their law enforcement partners have brought to successful conclusion the investigation and prosecution of numerous health care fraud schemes. In addition to these, numerous audits, evaluations and other coordinated oversight efforts yielded recoveries of overpaid funds, and prompted changes in Federal health care programs that reduce vulnerability to fraud. During FY 2004, the many significant HCFAC Program accomplishments included the following:

Fraud Issues

Pharmaceutical Companies Fraud

- Pfizer, a division of the Warner-Lambert Company, paid $430 million in fines and settled its FCA liability for illegal marketing conduct and fraudulent promotion of the drug Neurontin for uses that were not approved by the U.S. Food and Drug Administration (FDA). Neurontin was approved by the FDA in December 1993 solely for adjunctive or supplemental anti-seizure use by epilepsy patients. Under the provisions of the Federal Food, Drug and Cosmetic Act,
  21 U.S.C. § 301, et seq., a company must specify the intended uses of a product in its new drug application to FDA. Once approved, the drug may not be marketed or promoted for so-called "off-label" uses - any use not specified in an application and approved by FDA. However, Warner-Lambert's strategic marketing plans, as well as other evidence, showed that the company aggressively marketed Neurontin to treat a wide array of ailments for which the drug was not approved. The company promoted Neurontin for the treatment of various pain

disorders, Amyotrophic Lateral Sclerosis (ALS, a degenerative nerve disease commonly referred to as Lou Gehrig's Disease), attention deficit disorder, migraine, drug and alcohol withdrawal seizures, and restless leg syndrome.

Warner-Lambert promoted Neurontin for unapproved uses even when scientific studies did not demonstrate effectiveness. For example, the company promoted Neurontin as effective for use as the sole drug (monotherapy) for epileptic seizures, even after the FDA specifically had not approved monotherapy use. Similarly, Warner-Lambert falsely promoted Neurontin as effective for treating bipolar disease, even when a scientific study demonstrated that a placebo worked as well or better than the drug. As a consequence of the unlawful promotion scheme, patients who received Neurontin for unapproved and unproven uses had no assurance that their doctors were exercising their independent and fully-informed medical judgment, or whether the doctor was instead influenced by misleading statements made by, or inducements provided by, Warner-Lambert.

Warner-Lambert pleaded guilty to felony violations of the Federal Food, Drug, and Cosmetic Act, and paid a criminal fine of $240 million, the second largest criminal fine ever imposed in a health care fraud prosecution. The company also settled its Federal civil FCA liabilities by paying the United States $83.6 million, plus interest, for losses to the Federal portion of the Medicaid program, and resolved its civil liabilities to the fifty states and the District of Columbia by paying $68.4 million, plus interest, for losses to the state Medicaid programs. In addition, Warner Lambert paid $38 million to fund a remediation program, to be administered by state consumer protection offices, to address harm caused to consumers. Finally, Pfizer Inc, Warner-Lambert's parent company, agreed to comply with the terms of a corporate compliance program, designed to ensure that the changes Pfizer, Inc. made after acquiring Warner-Lambert in 2000 are effective, and that the company will detect and correct any future off-label marketing conduct on a timely basis. In addition, Warner-Lambert agreed to a state court injunction barring the improper conduct that was the subject of the state's Consumer Protection Division's investigation.

- Schering Sales Corporation, a sales and marketing subsidiary of drug manufacturer Schering-Plough Corporation, pleaded guilty and paid a $52.5 million fine on charges that it paid a health maintenance organization (HMO) a kickback to induce the HMO to keep Schering's drug, Claritin, on its formulary (a list of drugs that the HMO covers for its beneficiaries). Schering-Plough also settled its FCA liability and paid the United States, 50 state Medicaid programs, and certain Public Health Service (PHS) entities, approximately $293 million for failing to report the company’s true best price for Claritin to the Medicaid programs. At the same time, Schering-Plough entered into a Corporate Integrity Agreement, or CIA with the HHS/OIG to correct its government pricing and Medicaid rebate reporting failures.

In the late 1990s, Claritin was Schering's best-selling drug. Claritin was substantially more expensive, however, than its biggest competitor, Allegra. When one of Schering's best customers demanded a price reduction in Claritin -- because it cost the HMO millions of additional dollars a year to purchase Claritin instead of Allegra -- Schering refused, in part, because it knew that it then would have to lower the Claritin price for the Medicaid programs. Under the Medicaid Drug Rebate Statute, drug manufacturers are required to report their "best prices" to the Federal Government and to pay quarterly rebates to Medicaid to ensure that the nation's insurance program for the poor receives the benefit of favorable drug prices offered to other large purchasers of drugs. As a participant in the Medicaid Rebate Program, Schering was required to report its "best price" for and to pay rebates on Claritin. Similarly, under the provisions of the PHS drug pricing program, Schering was required to charge PHS entities such as AIDS drug programs and community health centers a discounted price, based in part on the Medicaid price.

After the HMO removed Claritin from its formulary, Schering offered to make up the difference in price between Claritin and Allegra by offering the HMO a $10 million package of added value, in lieu of an actual price reduction on Claritin. The United States alleged that, as part of this "value added" package, Schering offered to provide $3 million worth of deeply discounted Claritin Reditabs, health management services at far below fair market value, and an interest free loan in the form of prepaid rebates. Schering also offered to pay an annual fee of 2% of the annual gross sales of Schering drugs to the HMO, or approximately $2.4 million, disguised as a "data fee" in order to give the appearance that the fee was a fair market value transaction rather than a hidden inducement to the HMO to keep Claritin on its formulary.

Schering also provided, to another HMO, a risk share arrangement in which Schering covered a portion of the managed care customer's respiratory drug costs, provided deep discounts on other Schering products, provided payment and services for Internet development, and provided an interest free loan in the form of prepaid rebates. Because of Schering's failure to account for these discounts in its reported best price for Claritin, the Medicaid program and PHS entities paid far more for Claritin from 1998-2002 than Schering's two managed care customers.

- In an unrelated matter, Schering-Plough Corporation, Schering Corporation, and Warrick Pharmaceuticals paid the United States and the state of Texas $27 million to settle allegations that Warrick, a division of Schering-Plough, submitted false pricing information for its generic line of allergy and respiratory drugs. The government alleged that Warrick's manipulation of wholesale acquisition costs resulted in inflated claims for Federal and Texas Medicaid funds.

Misbranded Pharmaceutical Fraud

- Two defendants in Idaho who ran clinics purporting to treat spinal injuries and other illnesses, were sentenced to 51 months in prison, and more than $800,000 in restitution. The Idaho residents were indicted on 28 counts of conspiracy, wire fraud and misbranding drugs. One of the defendants fled to Mexico and was a fugitive for almost two years before turning himself in and pleading guilty. The other defendant pleaded guilty and was sentenced to serve 33 months imprisonment. The defendants owned a clinic in Nampa, Idaho, and operated a website that promoted a product called Neuralyn. More than 150 patients, mostly paraplegics or quadra-plegics, paid up to $10,000 to come to Nampa or affiliated clinics in Utah and Colorado to be treated. Patients were told that Neuralyn was 85 to 95% successful and could enable them to move or even walk again by regrowing nerve cells. They were told, falsely, that the defendant was a medical doctor with training in biochemistry, that Neuralyn had undergone clinical studies, and that a patent application and FDA approval were pending. Neuralyn contained a topical anesthetic that gave temporary relief and led patients to believe they were improving. The defendants charged $300 to $500 for a vial of Neuralyn, which cost them only $15. The pharmacist who made the Neuralyn pleaded guilty to conspiracy to deliver a misbranded drug in interstate commerce with intent to defraud. The pharmacist cooperated, was given five years probation, and paid restitution.

  The participating states, also victimized by this scheme, consisted of Alabama, Arizona, California, Colorado, Connecticut, Delaware, Georgia, Idaho, Indiana, Kentucky, Louisiana, Maine, Maryland, Michigan, Mississippi, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Tennessee, Texas, Utah, Virginia, Vermont, Washington, West Virginia, Wyoming; and the District of Columbia. The settlement covered the time period from January 1, 1997 to December 31, 2001. This settlement was reached through the efforts of Federal investigators and prosecutors, and the state Medicaid Fraud Control Units in the affected states.

Pharmaceutical Distribution Fraud

- Eleven defendants and two companies, including five physicians, were convicted of conspiracy to distribute controlled substances and related offenses, in the Eastern District of Virginia, in connection with their operation of illegal internet pharmacies. Many of the defendants had the proceeds of their unlawful activity seized. Over $2.3 million has been ordered to be seized, and approximately $4 million in cash and assets are subject to a final order of seizure. The defendants operated a number of websites through which they unlawfully distributed and dispensed millions of pills, including phendimetrazine, a Schedule III weight loss stimulant sold by its brand name Bontril, phentermine and Meridia (Schedule IV weight loss drugs), and Viagra, Xenical, and Celebrex. Customers who ordered drugs from the websites were not required to

provide a prescription before receiving the controlled substances. Instead, customers filled out an on-line questionnaire and chose the type, quantity, and dosage they wanted. The prescriptions were dispensed under the authorizations of co-conspirators through pharmacies owned by other co-conspirators. For a prescription to be valid, it must be issued for a legitimate medical purpose by an individual acting in the usual course of the professional practice. The prescriptions authorized by the physicians were not valid because they did not result from a legitimate doctor-patient relationship. Other than the on-line questionnaires, the physicians did not have any contact with the people ordering the medication, and did not monitor, or provide any means to monitor, medication response, weight loss or weight gain.

- Two pharmacists were convicted on charges in Texas, related to the operation of an internet pharmacy and the illegal dispensing of controlled substances. Online customers of the internet pharmacy could simply access the website, complete a questionnaire, and pick their controlled substance of choice. The pharmacy found doctors willing to sign prescriptions without examining the patient in exchange for "per prescription" payments. More than 38,000 prescriptions for controlled substances were written or filled in defendants' pharmacies, with roughly $5.6 million in pharmacy income from the sale of controlled substances. Although a Texas State Board of Pharmacy Inspector advised one of the defendants that prescriptions written without a valid doctor/patient relationship were invalid, the defendant moved to Oklahoma and set up a similar internet pharmacy there.

- Neways, Inc., distributor of BioGevity - an oral spray with human growth hormone (HGH), was sentenced to pay a $500,000 criminal fine and to forfeit $1.25 million. Although sale of HGH for human consumption is illegal without a prescription, Neways distributed HGH without a doctor's order, touting it as having a rejuvenating effect. The sentencing of Neways concludes the first prosecution in the United States of a company that distributed an oral spray containing HGH. HGH is a hormone produced by the pituitary gland that regulates growth. An adult misusing HGH is at risk of developing symptoms of the disease acromegaly such as enlargement and distortion of facial features, hands and/or feet, excessive growth of parts of the skull, thickening of the skin, development of hypertension, muscle weakness, enlargement of internal organs (including the heart, liver and spleen) and other syndromes, some of which are irreversible and possibly fatal.

False Prescriptions

- Rite Aid Corporation, a national retail pharmacy chain, paid the United States $5.6 million and $1.4 million to participating states (a total of $7 million) to settle allegations that the company submitted false prescription claims to government health insurance programs. The United States alleged that Rite Aid billed government health care programs (Medicaid, TRICARE and the Federal Employee Health Benefits Program (FEHBP)) for drugs that were never delivered to beneficiaries of the government health care programs and were later returned to stock.

Durable Medical Equipment Fraud

- Abbott Laboratories, Inc. paid the Federal Government $382 million and the 50 states and the District of Columbia a total of $32 million to resolve claims that its Ross Products Division defrauded the Medicare and Medicaid program over a 10-year period in connection with enteral feeding equipment. CG Nutritionals, Inc. (CG), a part of the Ross Products Division, pleaded guilty to obstructing a criminal investigation of health care offenses, paid a $200 million criminal fine, and was placed on 5-years of probation. In the settlement agreement resolving FCA liability, the United States alleged that Ross provided enteral infusion pumps at no charge to some of its customers, primarily nursing home suppliers, then advised the suppliers how to disguise the true cost of the pumps when the suppliers billed the government.

- The United States also contended that up-front payments, signing bonuses, conversion bonuses, and education bonuses were offered to its customers to induce them to sign long term contracts for enteral products that were ultimately reimbursed by Medicare. The Medicare and Medicaid Anti-kickback Statute forbids the payment of remuneration to induce the referral of Medicare or Medicaid patients. As part of the settlement, CG will be permanently excluded from participation in the Medicare and Medicaid programs. Abbott also entered into a 5-year CIA with the HHS/OIG, which required Abbott to reform the sales and marketing practices of its enteral feeding operations. The case arose out of "Operation Headwaters," a 3-year investigation into the illegal practices of durable medical equipment (DME) manufacturers.

- The president and owner of an Indiana DME and pharmaceutical supplier was sentenced to

  51 months imprisonment and ordered to pay over $1.9 million in restitution for health care fraud, mail fraud and unlawful kickbacks. The defendant is currently undergoing criminal forfeiture of assets, including a $1 million home and assets of two related businesses. The defendant had billed Medicare, Medicaid, and TRICARE for injectable solutions, intravenous (IV) therapies, and other selected services and supplies in grossly excessive quantities.

- St. Francis Hospital, Inc., a South Carolina hospital, agreed to pay $9.5 million to resolve Medicare billing improprieties in its home health, hospice, and DME programs. After conducting an internal investigation and audit, St. Francis discovered significant error rates and documentation lapses in its claims submitted to Medicare. The hospital subsequently disclosed these findings to the HHS/OIG under its Provider Self-Disclosure Protocol. This settlement represents the largest to date brought solely under the Civil Monetary Penalties (CMP) Law.

- Seven individuals in Miami, Florida were sentenced for their participation in a multi-million dollar conspiracy to defraud Medicare and launder the proceeds of the fraud. The scheme resulted in approximately $5 million in false claims to Medicare for power wheelchairs.

Kickbacks were paid to patients to induce them to act as fictitious power wheelchair recipients. In some cases, the conspirators staged deliveries of wheelchairs to the patients, and, after photographing the patient in his or her new wheelchair, took away the chair or retrieved it later. All seven defendants pleaded guilty prior to trial. The two organizers of the conspiracy were sentenced to prison terms of 87 months and 53 months, respectively. The other five received prison terms ranging from 1 year and 1 day to 78 months. The organizers and their top patient recruiter were ordered to pay $1.7 million in restitution. The four other defendants were held responsible for paying restitution in amounts ranging from $406,000 to $867,000, as a portion of the joint restitution figure.

- Four defendants, including a physician, were convicted in Los Angeles, California of charges of participating in a health care fraud scheme that sought approximately $2.6 million from the Medicare program for DME, including motorized wheelchairs, wheelchair accessories and hospital beds that were not medically necessary and, in many cases, were never delivered. One of the defendants, the owner of a Santa Monica wheelchair repair shop, paid patient recruiters, or "cappers," a fee to identify and bring Medicare beneficiaries to a local physician's clinic. The physician convicted as part of the scheme would have his physician's assistant examine the patients brought by the "cappers" in exchange for kickbacks up to $500 from the repair shop owner, and would sign Certificates of Medical Necessity authorizing Medicare payment for a motorized wheelchair, hospital bed, or other equipment for the patients. The repair shop owner would then use the Medicare beneficiary information and the Certificates of Medical Necessity to bill Medicare for unneeded medical equipment, which frequently was never delivered to patients. The shop owner billed Medicare primarily for motorized wheelchairs, for which Medicare typically reimbursed the seller approximately $4,000 to $8,000 per chair.

- Five defendants were convicted in the Northern District of Texas as a result of "Operation Roll Over," an investigation of a multi-million dollar Medicare fraud scheme that involved the fraudulent billing of motorized wheelchairs to Medicare. Recruiters working for the suppliers told Medicare beneficiaries that, in exchange for their Medicare information, they could receive free scooters and electric wheelchairs. The suppliers then used the patients' Medicare information to file fraudulent claims. Some of the Medicare beneficiaries understood they were getting scooters, and actually received scooters, but the wheelchair suppliers billed Medicare for the substantially more expensive motorized wheelchairs. Sometimes Medicare beneficiaries received written notification from Medicare that they had received a motorized wheelchair when, in fact, they had never asked for one nor received one. Typically, the defendant wheelchair suppliers would bill Medicare from $8,000 to $10,000 for motorized wheelchairs, for which they would receive approximately $5,000 from Medicare. The defendants were charged with health care and mail fraud, and money laundering. Several luxury vehicles and $7 million in proceeds were seized in connection with the fraud scheme.

- A defendant in Florida was sentenced to 37 months in prison and ordered to pay $1 million in restitution for health care fraud. The defendant operated and controlled four different DME companies using "straw nominee" owners to conceal the defendant's true identity.

The defendant submitted claims to Medicare for power wheelchairs that were either not provided,

were used or refurbished but billed as new, or were exchanged for less expensive scooters. The defendant also billed for the equipment repairs and paid kickbacks for wheelchair referrals. In 1997, the defendant was convicted in state court of Medicaid provider fraud in connection with using the same DME scheme.

Physician Fraud

- An Indiana physician was sentenced to 7-years incarceration (with 3 years suspended) for a scheme involving intimidating Medicaid beneficiaries by telling them they would lose their benefits if they did not make cash payments.

- A Norwalk, Connecticut pediatrician pleaded guilty to charges of health care fraud and tax evasion as a result of "Operation Free Shot," an investigation coordinated by the FBI's and HHS/OIG's Health Care Fraud Task Force which focuses on Connecticut health care providers who bill Medicaid and other insurance programs for childhood vaccines the providers received free-of-charge from the joint federal/state Vaccines For Children (VFC) program. The physician also entered into a civil settlement agreement with the United States and the State of Connecticut to resolve the civil liability for submitting claims to Medicaid for vaccine doses received free from the VFC program from 1997 through 2002. As part of the civil settlement, the defendant agreed to pay double damages in the amount of $318,000 to the United States and the State of Connecticut to reimburse the Medicaid program, and to reimburse the private insurance companies improperly billed (in the amount of approximately $230,000). In order to resolve the tax evasion charges, the defendant also agreed to pay all back taxes, penalties, and interest, totaling approximately $700,000.

- After a three and a half week trial, a Federal jury convicted a California psychologist of health care fraud, mail fraud, and making false statements for billing Medicare more than $1.3 million in services he did not provide to developmentally disabled patients. The psychologist, who had fired his attorney on the first day of trial and represented himself, failed to appear in court for the jury verdict, and was taken into custody the next day on a bench warrant. The psychologist submitted false claims for fictitious psychological services to a Medicare insurance carrier, and then engaged in an elaborate scheme to launder the money and conceal the fraud from the Medicare program. After the Medicare carrier challenged the validity of his claims, the psychologist began billing in the name of a corporation, which he alleged was a group practice with two other psychologists. The two psychologists testified at trial that they were not part of a group practice corporation. The psychologist set up a series of six entities through which he passed fraudulently obtained Medicare funds.

Home Health Care Fraud

- A Cleveland doctor who operated a medical practice named "House Calls Unlimited" was convicted of health care fraud for billing Medicaid and Medicare for in-home visits he did not make from 1999 through 2001. The defendant claimed to have made house calls on days the defendant was out of state, and billed for more than 24 hours of care in a single day. In addition, the defendant charged higher rates for private house calls when, in fact, patients were seen in group homes or in the defendant's home. The defendant also claimed to have made visits that were actually made by an unlicenced individual.

- Three defendants and a Michigan home health agency (HHA) were ordered to pay $866,000 in restitution for conspiracy to commit health care fraud and mail fraud. Two of the defendants, the president of the HHA and a director for the HHA, billed Medicare and a private insurer for the construction of their luxury home, including contractors' salaries and building materials and included these costs on the HHA's cost report. The two defendants were sentenced to respective terms of 48 months and 30 months in prison, and each was ordered to pay a $100,000 fine. The general contractor, who was listed as a ghost employee on the HHA's cost reports, was also sentenced to 15 months in prison. The HHA was ordered to pay a $10,000 fine.

- Banner Health, headquartered in Phoenix, Arizona, paid the United States $6.1 million to settle allegations that the company submitted false claims to Medicare to obtain reimbursement for home health care visits by employees at its Wyoming facilities. The government alleged that Banner Health, formerly known as Lutheran Health Systems, filed claims that were either not reasonable and necessary, or for which the amount, frequency and duration of services were not reasonable and necessary. The settlement is one of the largest recoveries by the United States in Wyoming.

Clinical Laboratory Fraud

- The owner of a clinical laboratory in Decatur, Illinois, received a sentence of five years imprisonment for mail fraud related to the lab's fraudulent billing to Medicare and Medicaid and was ordered to pay restitution of $2.5 million. The defendant admitted programming the laboratory's billing computer to bill Medicare and Medicaid for a urinalysis test at a higher rate than the rate for the test that was actually performed. Additionally, each time the test was performed, four additional tests were billed under separate codes, even though none of these tests were performed. The defendant admitted that the billing fraud continued for over three years.

- The owner of a medical testing laboratory extradited from the Philippines pleaded guilty to

defrauding the Medicare program by submitting bills for blood testing that was never performed. The lab owner admitted the lab submitted fraudulent bills to the Medicare and California Medicaid programs for tests for RBC Protoporphyrin (a test that detects iron deficiency and lead poisoning), Thin Layer Chromatography (a test used to detect drug metabolytes), Chemiluminescent Assay (a test useful in the identification of chlamydia and tuberculosis), and Sedimentation Rate (a test used to measure inflammation and infection in rheumatism patients). The laboratory did not have the ability to perform these tests. In the course of seventeen months, the lab submitted approximately $2.2 million in fraudulent bills. Medicare paid approximately $1.3 million of those claims.

Ambulance Services Fraud

- A Georgia patient ambulance transport company, First Med EMS, Inc., and its owner and director were sentenced on charges of conspiracy to defraud Medicare and Medicaid. The defendants submitted claims for emergency transport on behalf of individuals who did not qualify to receive such transportation. Moreover, multiple patients were transported at the same time, sometimes "stacking" patients in the front seat, but were billed as individuals. Patients were also transported in vehicles that were not licensed as ambulances, and accompanied by individuals who were not licensed EMS personnel. One of the defendants was sentenced to 30 months in prison, and the other was sentenced to 21 months in prison. The company was ordered to pay a $650,000 fine. All were ordered to pay $959,000 in joint and several restitution.

Physical Therapy Fraud

- Eight defendants in Houston, Texas were convicted for their roles in a scheme to defraud Medicare and the Texas Medicaid program at physical therapy clinics. Several of the physical therapy technicians were not licensed and had little or no experience in providing physical therapy treatments. A physician convicted in connection with the scheme approved Medicare/Medicaid beneficiaries to receive therapy without examining the patients to determine if they qualified for physical therapy, and failed to supervise the therapy treatments as required under Medicare and Medicaid guidelines. The physician was sentenced to 5 years in prison and ordered to pay restitution to the Texas Medicaid program in the amount of $1.39 million.

Medicare Contractor Fraud

- Highmark, Inc. entered an agreement to pay $1.5 million to resolve its liability under the civil FCA. The company's Veritus division, a Medicare contractor, allegedly altered Medicare claims information to inflate its scores during performance evaluations of the contractor by Medicare. Highmark disclosed the wrongdoing to the Government.

Teaching Hospital Physicians' Fraud

- A four year investigation into billing practices in the University of Washington Medical System ended with the University's physician practice plans agreeing to pay $35 million in restitution, damages and penalties to the state and federal governments for overbilling Medicare and Medicaid. This FCA settlement is the largest ever paid by a practice group related to a teaching hospital for failing to comply with Federal billing regulations. As a result of the investigation, two University physicians were convicted of criminal charges in connection with the fraud, and a former University neurosurgeon pleaded guilty to obstruction of a Federal criminal health care investigation. In addition, a University-affiliated nephrologist pleaded guilty to health care billing fraud and admitted engaging in fraudulent conduct spanning approximately 11 years during which the defendant wrote notes in patients' dialysis records indicating that he was present when he was not.

Nursing Home Registry Fraud

- In Maryland, a registered nurse pleaded guilty to operating a scheme to defraud area nursing homes by making false representations to the nursing homes that the defendant provided them with state-licensed and certified employees from the defendant's health care staffing company. The nurse's company had provided temporary nursing staff to nursing homes, hospitals, patients' homes and doctors' offices, including licensed practical nurses (LPNs), registered nurses (RNs), certified nursing assistants (CNAs), and geriatric nursing assistants (GNAs). Under Maryland law, the company was required to verify the licensure and status of the LPNs, RNs, and GNAs before dispatching these workers to health care facilities to render temporary nursing support. In fact, many of the licenses the company provided to its client nursing homes were falsified, altered, or forged. When law enforcement agents executed search warrants at the defendant's home and business, they found more than 60 "cut and paste" documents containing the names of several of the company's employees that had been altered, blocked out, or "corrected" with white-out to make the documents appear as bona fide licensing and certification documents from the State of Maryland.

Podiatry Fraud

- An Orange County, California podiatrist was convicted on 26 charges of fraudulently billing Medicare for more than $800,000 in procedures that were never performed. The evidence presented at trial showed that the podiatrist used the names and Medicare beneficiary numbers belonging to a few elderly patients to create and submit false claims for services that were never performed. The defendant submitted claims for daily or almost-daily surgical procedures and casting on these same patients for months at a time. The investigation began when a Medicare

beneficiary reviewed a Medicare statement, noticed that the podiatrist had billed Medicare for more than 70 procedures never performed, and called Medicare's hotline number to complain. When these patients were interviewed, they stated that they only saw the defendant once every two weeks or once a month, and then they only received toenail clippings.

Medicare Cost Report Fraud

- Tenet Healthcare Corporation, one of the largest hospital companies in the country, agreed to pay the United States $22.5 million to resolve FCA allegations that North Ridge Medical Center, one of its facilities in Fort Lauderdale, Florida, improperly billed the Medicare program for millions of dollars for referrals provided by doctors with whom the hospital had prohibited financial arrangements. The settlement also resolved the government's allegations that the hospital had requested improper reimbursements on the cost reports it submitted annually to the Medicare program. The settlement was the largest FCA recovery the United States has obtained to date from a single hospital arising out of alleged violations of the "Stark Statute," which prohibits hospitals from billing Medicare for services rendered to patients by doctors with whom the hospital has a financial relationship, unless the financial relationship falls within specified exceptions.

Quality of Care Issues

Another area in which collaboration among the Federal authorities responsible for health oversight has proved most effective has been in enforcement and oversight of issues relating to quality of care, as demonstrated by the following:

- The owner of three Louisiana nursing homes pleaded guilty in FY 2004 to health care fraud and pension fund fraud in connection with the diversion of millions of dollars from patient care at the homes. The defendant admitted defrauding the Federal Government by failing to provide the nursing home residents with adequate staffing, adequate services (including rehabilitative, medical, pharmaceutical, dietary, transportation, activity and social services), adequate supplies (including linens, medical and housekeeping), or a preventative maintenance program for equipment critical to providing an environment that enhanced the residents' quality of life. The conviction was the first criminal Federal health care fraud conviction of a nursing home owner for failing to provide care and services to nursing home residents. In addition to receiving the maximum sentence available under the sentencing guidelines, the defendant forfeited a 150-acre estate in Folsom, Louisiana, a private residence, and over 60 pieces of heavy construction equipment and vehicles used to improve properties owned by the defendant. The defendant was ordered to pay restitution out of the proceeds of the sale of the forfeited properties to various victims of the fraud. As part of the fraud scheme, the defendant had diverted money from the nursing homes to a property development company the defendant owned, and to personal use,

despite representations to the Medicare program that the money would be used to provide services to the residents of the nursing homes and to pay the homes' vendors. The defendant also pled guilty to charges that the employee pension fund had been improperly handled. Instead of putting the employees' 401(k) money into the employees' pension plans, the money was used to pay personal expenses and obtain an unauthorized loan from the pension plan.

- The defendant, a dentist in New York, pleaded guilty to mail fraud and false statements for filing numerous fraudulent claims to dental benefit plans for dental work that was never performed. The defendant maintained phony logs that indicated that the services had been provided as claimed. Further, various patients made statements indicating that the doctor increased earnings by performing root canals and other oral surgeries on patients who did not need the treatments. The dentist was sentenced to serve 63 months in prison (16 months of which was suspended) and ordered to pay $225,000 in restitution.

- In South Carolina, the remaining five physicians from a pain management center were sentenced for their roles in defrauding the Government. They were the last of ten individuals to be sentenced in a case that resulted in a total of more than 70 years imprisonment and restitution of approximately $811,000. The doctors at the center prescribed controlled substances outside the usual course of medical practice and forced unnecessary tests on patients in order to submit fraudulent claims to Medicare and other health care plans. Narcotics were provided to patients after little or no physical exam, and doctors met with more than one patient at a time but billed for individual rather than group visits in an effort to drive up the clinic's revenue.

- A registered nurse in the Emergency Department at Evans Army Community Hospital at Fort Carson Army Base in Colorado was sentenced to 60 months in prison for tampering with a consumer product that affected interstate commerce. On 300 occasions, the defendant gained access to sterile syringes containing morphine and Demerol meant for patients in the emergency room. The defendant withdrew the contents of those syringes into another syringe for self use. The defendant would then refill the syringes with saline, Nubain, or Phenergan and return them to the emergency's rooms medication distribution system for future patient use. The refilled syringes were later used to treat emergency room patients.

The achievements discussed above and throughout this report reflect the culmination of investigations that have been ongoing for several years. A more detailed description of other accomplishments of the major Federal participants in the coordinated effort established under HIPAA follows. While information in this report is presented in the context of a single agency, most of the accomplishments described herein reflect the combined efforts of HHS, DOJ and federal, state, local, and private insurance partners in the anti-fraud efforts.

FUNDING FOR DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Certain of the funds appropriated under HIPAA are, by law, set aside for Medicare and Medicaid activities of HHS/OIG. In 2004, The Secretary and the Attorney General jointly allotted $160 million to the HHS/OIG which is the statutory maximum permitted under HIPPA. This is equal to the amount allotted to the HHS/OIG in 2003. This represents approximately 80 percent of OIG's overall funding.

HHS/OIG conducted or participated in 801 prosecutions or settlements in 2004, of which 592 or 75 percent were health care cases. A number of these are highlighted in the Accomplishments section. During FY 2004, the HHS/OIG also excluded a total of 3,293 individuals and entities, barring them from participating in Medicare, Medicaid, and other Federal and state health care programs. In addition, the Department of Health and Human Services collected $141.4 million in disallowances of improperly paid health care funds, based on HHS/OIG recommendations.

Program Savings

Frequently, investigations, audits and evaluations reveal vulnerabilities or incentives for questionable or fraudulent financial practices in agency programs or administrative processes. As required by the Inspector General Act, the HHS/OIG makes recommendations to agency managers to address these vulnerabilities. In turn, agency managers recommend legislative proposals or other corrective actions that, when enacted or implemented, close loopholes and reduce improper payments or conduct. The net savings from these joint efforts toward program improvements can be substantial. During 2004, HHS/OIG estimates that such corrective actions resulted in health care savings (i.e., funds put to better use as a result of implemented legislative or other program initiatives) of approximately $ 27.3 billion -- more than $21.4 billion in Medicare savings, and more than $5.8 billion in savings to the Medicaid program. Additional information about savings achieved through such policy and procedural changes may be found at Appendix A to the HHS/OIG Semiannual Report, on-line at http://oig.hhs.gov/reading/semiannual.html.

Medicare Prescription Drug, Improvement, and Modernization Act

It is noteworthy that in late 2003, the President signed the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), a measure that will bring fundamental changes to Medicare reimbursement and coverage. MMA creates a voluntary outpatient prescription drug benefit and offers additional prescription drug benefits to Medicare beneficiaries. It authorizes health savings accounts and amends some of the HHS regulatory processes. In addition, MMA makes broad changes to Medicare's fee-for-service payment practices.

Most of MMA's changes will be phased in over the coming years; however, some savings were

realized almost immediately. For example, sections 303-305 of the MMA revised the payment methodology for certain drugs and biologicals covered under Medicare Part B. Under these provisions, beginning in 2004, reimbursement for these drugs was reduced by approximately 15 percent below their 2003 average wholesale prices. According to Congressional Budget Office analysis, the changes to the Part B payment methodology will result in a reduction of $15.2 billion in direct spending over 10 years. Savings for FY 2004 are estimated at $200 million. As another example of cost savings from legislative changes recommended in OIG reports, section 628 of the MMA froze annual updates for clinical diagnostic laboratory test fees for the period FY 2004-2008. Savings from these and similar MMA provisions totaled an estimated $980 million for FY 2004.

Exclusions

One important mechanism for safeguarding the care provided to program beneficiaries is through exclusion of providers and suppliers who have engaged in patient abuse or neglect or fraud. During 2004, the HHS/OIG excluded a total of 3,293 individuals and entities, many as a result of criminal convictions for crimes related to Medicare or Medicaid (584), or to other health care programs (165); for patient abuse or neglect (250); or as a result of licensure revocations (1,868). Among those excluded by the HHS/OIG were the following:

- A physician was excluded from participating in Medicaid for an indefinite period of time after he lost his license to practice medicine in New Jersey. The physician and his partner provided opiate detoxification services for addicted patients, following a detoxification procedure that was neither medically established nor recognized. Six patients died and others were hospitalized after undergoing this procedure in the physician's office.

- A licensed practical nurse in Arkansas was excluded permanently from participation in all Federal health care programs. The nurse was convicted on three separate occasions for crimes related to fraud, theft, breach of fiduciary responsibility and other financial misconduct in connection with delivery of health care services, and controlled substances offenses. While working at a nursing and rehabilitation center, the defendant stole controlled substances by signing out the drugs on the narcotics log. Sometimes the defendant falsely indicated the drugs were given to a specific patient when they were not; and sometimes the defendant gave the patient only a portion of the medication. On other occasions, the defendant did not chart the drugs to any patient. Additionally, the defendant was convicted for forging prescriptions in two separate jurisdictions.

- A marriage, family, and child counselor in California was excluded for 30 years based on a conviction for performing lewd and lascivious acts upon several of the defendant's male patients under the age of 14. The defendant was also sentenced to 22 years of incarceration, and the State Board of Behavior Sciences revoked the defendant's license.

- The OIG excluded an Ohio gynecologist for 60 years after being convicted for rape and sexual battery against 15 separate patients. The gynecologist was sentenced to 20 years for rape and 25 years for sexual battery.

- A Texas internist was excluded for 27 years based on a conviction for false claims to Medicare, Medicaid, FEHBP, and private health insurers. The physician instructed staff to randomly select 13 to 15 patient files per week, and to create "phantom" billings for these patients, even though the defendant had not seen or treated them on the claimed dates of service. The court ordered the defendant to pay more than $4 million in restitution and to serve a 60 month term of confinement. In addition, the defendant's Texas license to practice medicine was revoked.

- Two defendants were excluded for 15 years and 20 years, respectively, for executing a Medicare fraud scheme in which they visited nursing homes and community centers in Utah, Nevada, and Arizona to find Medicare beneficiaries to whom they could sell DME. To get the beneficiaries to release their names and Medicare identification numbers, the two defendants told flagrant lies, including that Congress had passed a "Fair Foot Bill," making shoes available to all Medicare beneficiaries at no charge. Thereafter, the couple did provide shoes to the beneficiaries, and then used the patients' Medicare information to fraudulently bill for numerous products. The court ordered one defendant to be imprisoned for 21 months and the other for 46 months. They were also ordered to pay $1.4 million in joint restitution.

- The HHS/OIG ultimately settled a proposed exclusion action involving the Redding Medical Center (RMC), a 246-bed hospital in Redding, California, formerly owned by Tenet Healthcare Corporation, Inc. for substandard quality of care. From 1999 through 2002, RMC allegedly performed multiple unnecessary cardiac surgeries on patients in the hospital. Tenet agreed to divest the hospital, and sell its assets to an unrelated party to avoid exclusion.

Studies, Audits, and Evaluations

The HHS/OIG continues to conduct studies, audits and evaluations of the Medicare and Medicaid programs for a variety of fraudulent or abusive activities. Among these are the following:

Drug Pricing

- The HHS/OIG has conducted studies of reimbursement by Medicaid and Medicare for a variety of pharmaceuticals, and found Medicare paying significantly more than other purchasers of these drugs. Some of these studies were mandated by the recent Medicare prescription drug bill. Others continued a long line of work in the area of pharmaceutical pricing studies.

DME

- HHS/OIG has published two studies of Medicare reimbursement for power wheelchairs. One study found that Medicare paid significantly higher rates for power wheelchairs than did individual consumers or suppliers. The second concluded that Medicare and its beneficiaries spend an estimated $178 million annually for wheelchairs that do not meet Medicare's coverage criteria. In response, CMS is considering revisions to its power wheelchair pricing rates, and possible changes to its coding to take into account the variety in power wheelchairs.

- The HHS/OIG found Medicare overpays for other DME also. For example, Medicare could have saved an estimated $499 million if it reimbursed for home oxygen equipment at rates paid by the FEHBP.

- The HHS/OIG found that the current Medicare payment for intraocular lenses of $150 per lens is not "reasonable and related to the cost," as required by law, and resulted in Medicare overpaying for these lenses by an estimated 40 percent. Further, the Medicare flat fee rate fails to take into account wide discrepancies in costs of varying types of lenses.

Rate Payment

- Medicare paid significantly higher rates—between 5 and 68 percent higher—for 10 drugs used in treating End Stage Renal Disease (ESRD) than did dialysis providers and facilities. CMS plans to use data from this report to set calendar year 2005 reimbursement rates for ESRD drugs.

- Medicare could have saved nearly $650 million in 2002 alone if it had reimbursed for two inhalation drugs used to treat respiratory conditions (albuterol and ipratropium bromide) at the rates paid by Medicaid for the same drugs.

- If Medicare carriers uniformly adopted a "least costly alternative" policy for the drug, Lupron (used to treat prostate cancer), the program and its beneficiaries could have saved an estimated $40 million per year. A "least costly alternative" policy provides that when there are medically equivalent treatments, Medicare would pay for the least costly treatment, since there would be no medical necessity for the more expensive products.

Duplicate Billings by Skilled Nursing Facilities

- Medicare sometimes pays twice for the same service: once to a skilled nursing facility under Medicare Part A and again to an outside supplier under Medicare Part B. Not all facilities and suppliers have established adequate controls to prevent improper billing for Part B services included in the Part A payment rate. As a result, the HHS/OIG identified $108.3 million in

improper payments to Medicare Part B suppliers during 1999 and 2000. It recommended that CMS recover the improper payments and instruct its Medicare contractors to establish and/or enhance billing controls.

Intergovernmental Transfers

- Some states utilize intergovernmental transfers to evade Federal/State matching requirements. Under these practices, states claim the Federal share of Medicaid funds for payments to public facilities; then the states turn around and require those facilities to return the funds to the state. An audit found that the State of Tennessee used intergovernmental transfers to require public facilities to return $398 million to the state; nearly half of these funds was placed in the state agency's reserve account, for use by the state legislature, with no assurance that the funds would benefit public facilities, as intended.

  An audit of a county nursing home in New York State disclosed that the facility received ample Medicaid payments to cover its operating costs; however, state and county intergovernmental transfer policies required the home to return a portion of those payments and left the home without adequate funding. Over a 3-year period, the home was allowed to keep less than half of its payments, a full $20 million less than its operating costs. As a result, the nursing home was seriously understaffed. This may have reduced the quality of patient care to the point that the home received a rating from the state indicating that the home's residents were in immediate jeopardy.

- States make disproportionate share hospital (DSH) payments to hospitals for the uncompensated costs of serving disproportionate numbers of low-income patients with special needs. OIG found that some states required hospitals to transfer millions in DSH funds to the state agency via intergovernmental transfers. OIG also found that one state – Alabama – made about $46 million in overpayments because the state did not comply with hospital-specific DSH payment limits. OIG noted that the state made DSH payments primarily to publicly owned hospitals because these hospitals could return the funds to the state. As a result, private hospitals were likely not reimbursed for all of their uncompensated care costs. The HHS/OIG recommended that another state – Ohio – refund about $47 million in overpayments because hospital-specific limits were exceeded and revise its state plan in accordance with Medicaid regulations.

- The HHS/OIG reviewed eight states to evaluate the potential savings to Medicaid if noncustodial parents were required to contribute toward their children's Federal and state Medicaid costs. Noncustodial parents could contribute an estimated $99 million, or 50 percent, of their children's Medicaid costs over a 1-year period.

HCFAC has been successful in building up a much-needed capacity to confront health care fraud involving the Medicaid program. This is critical because Medicaid is undergoing significant growth and its total budget (state and federal) now exceeds that of Medicare.

Industry Outreach and Guidance

- The core of the HIPAA guidance initiatives is an advisory opinion process through which parties may obtain binding legal guidance as to whether their existing or proposed health care business transactions run afoul of the Federal anti-kickback statute, the civil monetary penalties laws, or the exclusion provisions. During 2004, the HHS/OIG, in consultation with DOJ, issued 10 advisory opinions. A total of 114 advisory opinions were issued during the first 8 years of the HCFAC program.

- Many health care providers that enter agreements with the government to settle potential liabilities for violations of the FCA also agree to adhere to a separate CIA. Under these agreements, the provider commits to establishing a program or taking other specified steps to ensure its future compliance with Medicare and Medicaid rules. At the close of 2004, HHS/OIG was monitoring more than 345 CIAs.

Centers for Medicare & Medicaid Services

In 2004, the Centers for Medicare and Medicaid Services (CMS) was allocated $22.75 million to fund a variety of projects related to fraud, waste, and abuse in the Medicare and Medicaid programs. Of this amount, approximately $18 million was specifically dedicated to combat fraud in the State Children's Health Insurance Program (SCHIP) and Medicaid program. CMS has increased its efforts to use advanced technology to detect and prevent fraud and abuse and to ensure that CMS pays the right providers the right amount, for the right service on behalf of the right beneficiary. CMS fraud, waste, and abuse projects are described below:

Payment Error Rate Measurement (PERM) and SCHIP Pilot Project

- HCFAC funding enabled 30 states and the District of Columbia to participate in a pilot project which allows states to test a methodology to determine its improper payment error rate in its SCHIP and/or Medicaid programs. The methodology will allow CMS to use the results to calculate a national Medicaid and SCHIP error rate.

  In response to an all-state solicitation, CMS awarded grants to pilot test the PERM (Payment Error Rate Measurement) methodology. The District of Columbia and 30 states participating in this project are: Alabama, Alaska, Arizona, Arkansas, Colorado, Delaware, Florida, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Minnesota, Missouri, Nevada, New Mexico, New York, Oklahoma, Pennsylvania, South Carolina, South Dakota, Texas, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.

Medicaid/SCHIP Financial Management Project

- CMS hired and began training staff for Medicaid oversight work. The staff will review the state's Medicaid operating plans prior to the beginning of the fiscal year so that any problems or issues can be resolved before claims are submitted. They will also perform in-depth reviews of funding sources such as donations, taxes, certified public expenditures, intergovernmental transfers, and state and local appropriations to verify that they are allowable non-Federal funding sources. The goal is to eliminate the current need for CMS to disallow Federal Medicaid funding after it has already been spent by states and to identify any unallowable funding schemes or expenditures before they actually occur.

Financial Management Data Redesign Project

- CMS used HCFAC funding to develop and enhance an integrated financial management tool as part of a financial management and design project. The system that was developed from the original project has been renamed. It is now called the Transactions, Information Inquiry, and Program Performance System or TIPS. TIPS links existing CMS data systems and tools. This tool was developed through a contract with Enterprise Technology Partners (ETP). TIPS provides a "dashboard" view linking CMS' Medicaid/SCHIP financial monitoring and expenditure systems with other core data sets (statistical, administrative, and program features) with the overarching goal of better financial management of the Medicaid program and SCHIP.

Medicare-Medicaid Data Matching Project

- Beginning in 2003, HCFAC funds were allocated to CMS to expand a joint Medicare and Medicaid data-matching project from one to nine total states. The data-matching project was developed to examine health care claims data from health care programs that share common beneficiaries and providers, for aberrancies indicative of potential fraud or abuse. Continued operation of the California Medicare-Medicaid data-matching project has resulted in estimated savings and prevention of payments involving dollars formerly at risk (prior to the project), and recoupments of several million dollars. In 2004, CMS initiated Medicare-Medicaid data matching projects in eight other states - Texas, Illinois, North Carolina, Florida, New Jersey, Pennsylvania, Ohio and Washington, as well as continuing operation and maintenance of the original project in California. Of the eight expansion states; Texas, Illinois, North Carolina, Florida, New Jersey and Pennsylvania have been fully operational since May 2004. The other two expansion states, Ohio and Washington, are working closely with CMS and their respective Program Support Centers to reach full operational status as soon as possible.

Data Extract Project

- HCFAC resources were used in FY 2004 to make enhancements to the Health Care Information System (HCIS), used by DOJ, the HHS/OIG, and other program integrity stakeholders. The HCIS data warehouse now includes data on Skilled Nursing Facilities and Home Health Agencies.

Medicare + Choice Steerage and Discrimination Project

- The Medicare + Choice Steerage and Discrimination project is designed to develop a practical methodology for CMS to use in identifying potentially discriminatory plan benefits and/or marketing materials. In FY 2004, CMS defined several types of models for detecting steerage of beneficiaries and/or discrimination against beneficiaries on the basis of plan benefit design. CMS used five of these models to analyze 2004 plans and produce an interactive spreadsheet analysis tool for using the models.

Medicaid Audits

- In 2004, HCFAC funds were allocated to CMS to support a series of special Medicaid audits conducted by the HHS/OIG through an Interagency Agreement with CMS. Approximately 30 audits were undertaken in states and issue areas specified by CMS. The major targeted areas included: vaccines for children, institutions for mental diseases, family planning services in managed care, skilled professional medical personnel, and provider overpayments.

Office of the General Counsel

The Office of the General Counsel (OGC) was allocated $4.67 million in HCFAC funding for 2004 to support program integrity activities. These funds were used primarily for litigation activity, both administrative and judicial.

OGC accomplishments in 2004 include the following:

Suspensions

- OGC provided legal advice and review to CMS for more than 160 suspension actions, involving substantial amounts of Medicare funds.

Litigation

- In nursing home enforcement, OGC represented CMS in 461 new administrative cases before the Departmental Appeals Board (DAB) in 2004. CMP recoveries against nursing homes, due to favorable administrative decisions or negotiated settlements, totaled over $12 million. There were also approximately 30 new Federal court cases as a result of nursing home enforcement actions.

- Rulings in Woodstock Care Center v. Thompson and Meadow Wood Nursing Home v. Thompson. In these two decisions, a court of appeals upheld the authority of HHS to impose CMPs for two common and serious types of deficiencies in nursing homes: failure to exercise necessary precautions to prevent cognitively impaired residents from eloping from a facility and failure to exercise necessary precautions to prevent residents from becoming entangled in side rails on their beds.

Bankruptcies

- OGC continues to be heavily involved with CMS's bankruptcy workload. OGC protects Medicare funds by asserting CMS's recoupment rights to collect overpayments, by arguing to continue suspension or termination actions against debtors or by seeking adequate assurances from the bankruptcy court that CMS's interests in the debtor's estate will be protected, by arguing for the assumption of the Medicare provider agreements as an executory contract, and by petitioning for administrative costs where appropriate. OGC obtained almost $100 million in bankruptcy recoveries during FY 2004.

- In the single bankruptcy case of In re Sun Healthcare (Bankr. D. Del.), OGC obtained collection of $24 million in Medicare overpayments and almost $750,000 in CMPs, for over 400 bankrupt providers. OGC's actions in the bankruptcy case also enabled CMS to collect, through its fiscal intermediaries, over $9 million in overpayments from providers connected with Sun but not impacted by the bankruptcy, and over $3 million in postpetition Sun CMPs.

- OGC persuaded the U.S. Court of Appeals for the First Circuit in Holyoke Nursing Home, Inc. v. Health Care Financing Administration to reject the Third Circuit's approach and instead join the D.C. and Ninth Circuits in ruling that Medicare's right to recoup overpayments is not negated by a provider's filing for bankruptcy. This ruling is crucial to Medicare's ability to protect against a drain on the Medicare Trust Fund when providers seek bankruptcy protection.

Legal Guidance and Education

- OGC provided legal guidance and assistance in drafting regulations involving: home health agencies, provider enrollment, coordination of benefits and statistical analysis.

- OGC has advised the Home Health Task Force (HHTF) on issues ranging from payment suspension to termination proceedings, and has reviewed numerous requests for payment suspension and notices of termination of Medicare participation.

- OGC provided advice to CMS, represented CMS in administrative hearings, and assisted DOJ in defending CMS's decisions, concerning enforcement of the Medicare participation requirements for providers and suppliers, including hospitals, home health agencies, skilled nursing facilities, and community mental health centers.

MMA Clarifications

- OGC successfully defended the MMA clarifications, and their retroactive effect, in the U.S. Court of Appeals for the Fourth Circuit (Brown v. United States), in a challenge by a multi-employer group health plan (Auto Releasing v. Thompson), and in a Minnesota class action brought by Medicare beneficiaries (Timmerman v. Thompson).

Administration on Aging

In 2004, the Administration on Aging (AoA) was allocated $3.28 million in HCFAC funds to develop and disseminate consumer education information to older Americans, with a particular focus on persons with low health literacy, individuals from culturally diverse backgrounds, persons living in rural areas, and other vulnerable populations. AoA and its nationwide network of agencies supported community education activities designed to assist older Americans and their families to recognize and report potential errors or fraudulent situations in the Medicare and Medicaid programs.

Senior Medicare Patrol (SMP) Projects recruit retired professionals to educate and assist Medicare beneficiaries to detect and report health care fraud, error, and abuse in Medicare and Medicaid programs. According to the last performance information from the Assistant Inspector General for Evaluation and Inspections, over the 12-month period, ending June 30, 2004, the 57 SMP project volunteers educated over 440,000 beneficiaries in group and one-on-one sessions. As a result of educating beneficiaries, the projects received over 7,600 complaints, of which 1,700 were referred to Medicare contractors for follow-up. Over 800 of these complaints resulted in money recouped to the Medicare program or another action taken by the Medicare contractor or investigative agency. In total, SMP projects documented close to $194,000 recouped to the Medicare program during this period. The projects also reported $200,000 in savings to the Medicaid program, and savings of approximately $467,000 to beneficiaries.

While it is not possible to directly track all of the cases reported and dollars recovered through SMP community education activities, or quantify the "sentinel effect" in fraud costs avoided due to increased consumer awareness, a total of nearly $104 million has been reported as savings attributable to the program since its inception.

Health Resources and Services Administration

In FY 2004, $450,000 in HCFAC funds was allocated to the Health Resource and Services Administration, or HRSA, to support the overall operations and maintenance of the Healthcare Integrity and Protection Data Bank (HIPDB) program. The primary focus of the HIPDB is to prevent or reduce fraud and abuse in the medical system and to enhance quality health care by serving as a repository for collecting, maintaining, and reporting on final adverse actions taken against health care providers, suppliers, and practitioners. This information helps prevent practitioners, providers, and suppliers with problem backgrounds from moving from state to state unnoticed by licensing, government, and health plan officials, thus improving health care quality. It also assists law enforcement officials in their efforts against health care fraud and abuse.

FUNDING FOR DEPARTMENT OF JUSTICE

United States Attorneys

In 2004, the United States Attorney's Offices (USAOs) were allocated $30.4 million dollars in HCFAC program funds to support civil and criminal health care fraud and abuse litigation as exemplified in the Program Accomplishment's section. The USAOs dedicated substantial resources to combating health care fraud and abuse in FY 2004. HCFAC allocations have supplemented those resources by providing dedicated positions for attorneys, paralegals, auditors and investigators, as well as funds for litigation of resource-intensive health care fraud cases.

The 93 United States Attorneys and their assistants, or AUSAs, are the nation's principal prosecutors of Federal crimes, including crimes committed by health care providers. Civil attorneys in the USAOs are responsible for bringing affirmative civil cases to recover funds that Federal health care programs have paid as a result of fraud, waste, and abuse, with support in those cases designated by the Civil Division for joint handling. USAOs also handle most criminal and civil appeals at the Federal appellate level.

In addition to the staff positions funded by HCFAC, EOUSA's Office of Legal Education (OLE) uses HCFAC funds to train AUSAs and other Department attorneys, as well as paralegals, investigators, and auditors in the investigation and prosecution of health care fraud. In 2004, OLE conducted courses and presentations on health care fraud, including the Health Care Fraud Coordinator's Conference for Civil and Criminal AUSAs and Health Care Fraud for New AUSAs.

Criminal Prosecutions

In 2004, the USAOs received 1,002 new criminal matters involving 1,685 defendants, and had 1,626 health care fraud criminal matters pending,[4] involving 2,361 defendants. The USAOs filed criminal charges in 395 cases involving 646 defendants, and obtained 459 Federal health care related convictions. USAOs receive referrals of criminal health care fraud cases from a wide variety of sources, including the FBI, the HHS/OIG, state Medicaid Fraud Control Units, and other federal, state, and local law enforcement agencies.

Civil Matters

The USAOs use affirmative civil enforcement litigation to recover monies wrongfully taken from the Medicare Trust Fund and other taxpayer-funded health care systems, and to ensure that the Federal health care programs are fully compensated for the losses and damages resulting from such thefts. The FCA is one of the most important tools the USAOs use for these purposes. The FCA subjects those who knowingly present false claims for payment to the government, including health care providers who submit claims to Federal health care programs, to treble damages and civil penalties.

USAOs receive civil health care fraud referrals from a variety of sources, including from the Federal investigative agencies that refer criminal cases, and by means of qui tam complaints. Under the FCA, a qui tam plaintiff (known as a "relator") must file his or her complaint under seal in a United States District Court, and serve a copy of the complaint upon the USAO for that judicial district, as well as the Attorney General. USAOs routinely assign civil AUSAs to every qui tam case filed in their districts, as well as all matters referred by a law enforcement agency. In 2004, the USAOs opened 868 new civil health care fraud matters (including qui tam actions and matters referred by agencies) and had 1,362 civil health care fraud matters and cases pending. In order to maximize resources, Civil Division attorneys may become actively involved and participate with the USAOs in those qui tam cases that involve more than one district and potential recoveries substantially over one million dollars. In addition to these joint cases, USAOs are responsible in all other qui tam cases for investigating the relator's allegations and, where appropriate, litigating and/or settling the case. In 2004, USAOs filed or intervened in 269 civil health care fraud cases.

Civil Division

In 2004, the Civil Division was allocated $14.46 million in HCFAC funds to support civil health care fraud litigation, and an additional $1 million to administer the Nursing Home Initiative. Civil Division attorneys pursue civil remedies in health care fraud matters, working closely with the USAOs, the FBI,

[4]When a USAO accepts a criminal referral for consideration, the office opens it as a matter pending in the district. A referral remains a matter until an indictment or information is filed or it is declined for prosecution.

the Inspectors General, CMS, and other federal and state law enforcement agencies. Cases involve providers of health care services, supplies and equipment, as well as carriers and fiscal intermediaries, that defraud Medicare, Medicaid, TRICARE, FEHBP, and other government health care programs.

In FY 2004, the Division opened or filed a total of 303 health care fraud cases or matters. In addition to these new efforts, the Division pursued 514 existing cases or matters that remained open at the end of FY 2003. Division attorneys were actively involved in the recoveries described in the consolidated case recovery overview. In addition, the Division provided in-depth, multi-day, training to AUSAs nationwide on the FCA, including issues relating to the investigation and litigation of qui tam cases, and continued to provide training to DOJ and HHS components on a regular basis.

Civil Division attorneys litigate a wide range of health care fraud matters, including cases involving allegations of overcharging by hospitals, and other Medicare Part A institutional providers; similar claims against suppliers of DME and other supplies under Part B of Medicare; claims that doctors and others have been paid kickbacks or other remuneration to induce referrals of Medicare or Medicaid patients, in violation of the Anti-Kickback Act and Stark laws; claims of overpricing and illegal marketing of pharmaceuticals by drug companies and related entities; and allegations that nursing homes have failed to provide necessary care to the elderly. Among these are multi-district cases involving large health providers and suppliers that typically require coordination among affected Federal agencies, USAOs, state Medicaid Fraud Control Units and other state agencies, and various investigative organizations.

The Civil Division continues to staff and provide a critical coordination function in the FCA investigations alleging pharmaceutical pricing fraud against government health care programs. These matters involve hundreds of manufacturers and related entities, span multiple districts and present myriad legal and factual issues. Civil Division attorneys have spearheaded substantial efforts to share information and evidence, as appropriate, with the USAOs and other components of DOJ, as well as HHS components including the FDA. In addition, close communication with state Medicaid Fraud Control Units and Attorneys General is ongoing to ensure that federal and state investigations and litigation are coordinated.

In addition, Civil Division attorneys, working with attorneys in the Criminal Division and the USAOs, have played a critical role in coordinating and presenting the views of DOJ to the CMS as that agency drafts implementing regulations for the new Medicare prescription drug benefit passed as part of MMA. Civil Division attorneys also played a role in coordinating and presenting DOJ's views to the HHS/OIG as it interpreted and applied the Anti-kickback Statute and Stark laws (prohibiting physician self-referral). In addition, the Division worked with other components of DOJ to provide views on the Hospital Compliance Program Guide published by the HHS/OIG.

The Department's Nursing Home and Elder Justice Initiative is coordinated by the Civil Division. The Nursing Home and Elder Justice Initiative, among other things, supports enhanced

prosecution and coordination at federal, state and local levels to fight abuse, neglect, and financial exploitation of the nation's senior and infirm population. Through this initiative, DOJ also makes grants to promote prevention, detection, intervention, investigation, and prosecution of elder abuse and neglect, and to improve the scarce forensic knowledge in the field. DOJ additionally is pursuing a growing number of cases under the FCA involving providers' egregious "failures of care."

Civil Division attorneys continue to provide guidance and training to government attorneys in numerous subject matters, including to assure the Department's continued compliance with the HIPAA privacy rule. Also, the Civil Division continues to co-chair, with the Criminal Division, the National Level Health Care Fraud Working Group to coordinate the health care fraud enforcement activities of all concerned federal and state agencies.

Criminal Division

In FY 2004, the Criminal Division was allocated $1.58 million in HCFAC funds to support criminal health care fraud litigation. The Fraud Section of the Criminal Division develops and implements white collar crime policy and provides support for the Federal white collar enforcement community. The Fraud Section supports the USAOs with legal and investigative guidance and, in certain instances, provides trial attorneys to prosecute criminal fraud cases. For several years, a major focus of the Fraud Section has been to investigate and prosecute fraud in Federal health care programs.

The Fraud Section has provided guidance to FBI agents, AUSAs and Criminal Division attorneys on criminal, civil and administrative tools to combat health care fraud, and worked on an interagency level through: coordinating large scale multi-district health care fraud investigations; providing frequent advice and written materials on confidentiality and disclosure issues arising in the course of investigations and legal proceedings regarding medical records; monitoring and coordinating Departmental responses to major regulatory initiatives, legislative proposals, and enforcement policy matters; reviewing and commenting on numerous requests for advisory opinions submitted by health care providers to the HHS/OIG, and consulting with the HHS/OIG on draft advisory opinions per the requirements of HIPAA; working with CMS officials to promote more effective use of technologies and high-tech approaches for combating health care fraud and abuse, and working with USAOs and CMS to improve Medicare contractors' fraud detection and case development work; preparing and distributing to all USAOs and FBI field offices periodic updates on major issues, interagency initiatives, and significant activities of DOJ's health care fraud component organizations as well as periodic summaries of recent cases; and organizing and overseeing, in conjunction with the Civil Division, the National Level Health Care Fraud Working Group to address fraud in health care and managed care, as well as other interagency working groups formed to address specific cases and initiatives.

The Fraud Section has responsibility for handling and coordinating complex health care fraud litigation nationwide. In FY 2004, the Fraud Section handled or was involved in investigations of hospitals, medical equipment suppliers, and vocational rehabilitation and healthcare management services, as well as other health care providers. Examples of successful Fraud Section health care fraud prosecutions in 2004 follow:

- A wholly owned subsidiary of Crawford & Company, Inc., a provider of vocational rehabilitation and health care management services to insurance companies and self-insured entities, pleaded guilty to mail fraud stemming from a billing fraud scheme. From 1992 to 1999, Crawford entities over-billed clients by inflating the amount of time and expenses Crawford employees spent on clients' accounts. The court imposed an $8 million fine.

- As a result of an FBI undercover investigation, Augustine Medical, Inc., (AMI), a privately held, Minnesota manufacturer of medical devices, its former chief executive officer, its former general counsel, former director of reimbursement, former national sales manager, and an independent billing consultant, all pleaded guilty to criminal charges stemming from a scheme to increase AMI's market share so that AMI could increase its value and become a publicly-held corporation. As part of the scheme, AMI and the co-defendants instructed healthcare providers to fraudulently bill Medicare, resulting in a loss to Medicare of more than $6 million. AMI paid a fine of over $5 million and in a related civil settlement, agreed to pay $7.4 million to Medicare. In addition, AMI was permanently barred from doing business with Medicare.

Civil Rights Division

In FY 2004, the Civil Rights Division was allocated $1.98 million in HCFAC funds to support Civil Rights Division litigation activities related to health care fraud. The Civil Rights Division pursues relief affecting public, residential health care facilities. The Division has also established an initiative to carry out the Department's goals to eliminate abuse and grossly substandard care in Medicare and Medicaid funded nursing homes and other long-term care facilities.

The Division plays a critical role in the HCFAC program. The Special Litigation Section of the Civil Rights Division is the sole Department section responsible for the Civil Rights of Institutionalized Persons Act, 42 U.S.C. § 1997 (CRIPA). CRIPA authorizes investigation of conditions of confinement at state and local residential institutions (including facilities for persons with developmental disabilities or mental illness, and nursing homes) and initiation of civil action for injunctive relief to remedy a pattern or practice of violations of the constitution or Federal statutory rights. The review of conditions in facilities for

persons who have mental illness and for persons with developmental disabilities, and nursing homes comprises a significant portion of the program. The Special Litigation Section works collaboratively with the USAOs and HHS.

As part of the Department's Institutional Health Care Abuse and Neglect Initiative, and as an enhancement to the Department's ongoing CRIPA enforcement efforts, this year the Civil Rights Division initiated six investigations of public health care facilities, made findings of unconstitutional conditions regarding ten health care facilities, and secured consent decrees and settlement agreements involving seven health care facilities. A few examples of the Civil Rights Division's achievements include:

- The United States District Court for the District of Columbia ordered the District of Columbia defendants in Evans and United States v. Williams, to repay almost $1.2 million to persons with mental retardation and other developmental disabilities in the District's service delivery system. The District acknowledged that for years it had mishandled consumers' personal financial accounts. Several years ago, the District had reached agreement with the Civil Rights Division and the private plaintiffs in the Evans lawsuit that it would pay for an independent audit of consumer funds for a ten-year period. The auditor issued its final report in early January 2004. The Court Order represents the culmination of this audit and legal process and means that hundreds of persons with developmental disabilities will receive individual amounts owed to them as determined by the audit and set forth in the final report, ranging from a few dollars to several thousand dollars each.

  Through the course of its ongoing monitoring of the District's compliance with the Court's Orders in Evans, the Division has identified numerous irregularities and improprieties in the District's safeguarding of consumers' funds and possessions. Evans class members, who once lived at Forest Haven, the District's now-closed institution, as well as other consumers who receive support from the District's Mental Retardation and Developmental Disabilities Administration have mental retardation or other developmental disabilities. Many of them require assistance in managing their money, and, as a result, are vulnerable to monetary abuse and exploitation. The Division and its consultants also had found that defendants were not maintaining consumers' funds in interest-bearing accounts, providing consumers with their personal care allowances, ensuring consumers who were eligible for benefits were receiving them, nor properly accounting for burial set-aside monies.

- United States District Court in the Middle District of Louisiana entered a consent decree in United States v. Louisiana, involving conditions at Louisiana's two largest institutions for persons with developmental disabilities, Pinecrest and Hammond Developmental Centers. The decree resolves the Civil Rights Division's investigation, initiated in 1995, conducted pursuant to CRIPA, that uncovered egregious conditions. In one facility, various staff dragged a resident across the carpet, causing abrasions; kicked a resident; placed a blanket over a resident's head

and hit him; slapped a 50-year-old resident on the head and put a rag over her nose and mouth; and pulled a resident's hair with such force that her head literally jerked from one side of the pillow to the other. Other deficient conditions included inadequate medical and mental health care, inadequate rehabilitation services, and failures to serve residents in the most integrated setting appropriate to their individual needs.

- The Division announced the results of its investigation into the State of California's role in the unnecessary institutionalization of residents at Laguna Honda Hospital and Rehabilitation Center ("Laguna Honda"), in San Francisco, California this year also. The Department found evidence that the state is contributing to the unnecessary segregation of individuals with disabilities residing at the 1,200-bed nursing home. These findings are part of the Division's long-standing investigation into whether residents of Laguna Honda are being served in the most integrated setting appropriate to their needs, as required by the Americans with Disabilities Act of 1990 ("ADA"). The Division initiated its investigation of California following findings in May 1998 and April 2003 that San Francisco, which owns and operates Laguna Honda, unnecessarily isolates residents in violation of the ADA. The Division found evidence that California has failed to ensure that residents eligible for community placement have meaningful access to community alternatives. Instead, the state routinely authorizes placements without requiring adequate assessments evaluating the appropriateness of home- and community-based care. As a result, individuals are not informed of community options available in California and remain at Laguna Honda long after they become eligible for community programs and services. For example, one resident has been at the nursing home since 1991, after a traffic accident. The resident goes to work each day and uses public transportation. The resident needs support to find housing and adjust to community living. In June 2003, however, the state approved the resident's stay at Laguna Honda for another two years.

- The Division announced the results of its investigation into the conditions of confinement for adult patients at Metropolitan State Hospital, in Norwalk, California this fiscal year. In 2003, the Division issued findings regarding the child and adolescent patients at this state-operated facility. Of the approximately 825 patients, ranging in age from 11 to more than 80, roughly 100 are children and adolescents. The Division's investigation of the facility uncovered significant civil rights violations relating to deficiencies in care and services provided to patients. The facility frequently uses older psychotropic medications, with serious side effects, to sedate adolescent patients. One adolescent received 22 such psychotropic "as-needed" sedatives over a two-month period. Adult patients are routinely treated with psychotropic medication without an appropriate diagnosis. Also, Metropolitan does not conduct psychological testing in Spanish for patients whose primary language is Spanish. The State of California has acknowledged the need to take remedial actions and has reportedly commenced addressing the issues raised in the findings letters.

APPENDIX

Federal Bureau of Investigation
Mandatory Funding

> "There are hereby appropriated from the general fund of the United States Treasury and hereby appropriated to the Account for transfer to the Federal Bureau of Investigation to carry out the purpose described in subparagraph (C), to be available without further appropriation - (I) for fiscal year 2004, $114,000,000."

In FY 2004, the FBI was allocated $114 million in HCFAC funds for health care fraud enforcement. This yearly appropriation was used to support 825 positions (479 Agent/346 Support) in FY 2004, a decrease of 53 positions from the positions supported in FY 2003 (28 Agent, 25 Support). The
FY 2004 funding did not allow for cost of living increases, necessitating reductions in funded staffing levels. The number of pending investigations has shown steady increase from 591 cases in 1992 to 2,468 cases through 2004. FBI-led investigations resulted in 564 criminal health care fraud convictions and 693 indictments and informations being filed in state and Federal courts in FY 2004.

The FBI is the primary investigative agency involved in the fight against health care fraud that has jurisdiction over both the Federal and private insurance programs. With health care expenditures rising at three times the rate of inflation, it is especially important to coordinate all investigative efforts to combat fraud within the health care system. Nearly $1 trillion is spent in the private sector on health care and its related services and the FBI's efforts are crucial to the overall success of the program. The FBI leverages its resources in both the private and public arenas through investigative partnerships with agencies such as the HHS/OIG, the FDA, the Drug Enforcement Administration (DEA), the Defense Criminal Investigative Service, the Office of Personnel Management, the Internal Revenue Service and various state and local agencies. On the private side, the FBI is actively involved with national groups, such as the National Health Care Anti-Fraud Association (NHCAA), the Blue Cross and Blue Shield Association and the Coalition Against Insurance Fraud, as well as many other professional and fundamental efforts to expose and investigate fraud within the system.

Health care fraud investigations are the number three priority within the FBI's White Collar Crime Program. In addition to being a partner in the majority of investigations listed in the body of this report, the FBI continued the Outpatient Surgery Initiative to combat the growing problem of fraudulent surgeries performed at certain outpatient facilities in Southern California. This nationwide scheme has drawn participants from 48 of the 50 states who have traveled to California to have unnecessary surgery in exchange for a cash kickback, and has resulted in billings to the insurance companies in excess of

$750 million. The FBI partnered with the NHCAA to collect intelligence on the problem, and launched a nationwide investigation. To date over 90 subjects have been identified which involves the participation of 21 FBI Field Offices.

The majority of funding received by the FBI is used to pay personnel costs associated with the 825 funded positions. Funds not used directly for personnel matters are used to provide operational support for major health care fraud investigations and national initiatives currently focusing on pharmaceutical fraud and outpatient surgery centers. Further, the FBI continues to support individual investigative needs such as the purchase of specialized equipment and expert witness testimony on an as-needed basis.

Glossary Of Terms

The Account - The Health Care Fraud and Abuse Control Account

ACE - Affirmative Civil Enforcement

AoA - Department of Health and Human Services, Administration on Aging

ASBTF - Department of Health and Human Services, Assistant Secretary for Budget, Technology and Finance

ASC - Ambulatory Surgical Centers

AUSA - Assistant United States Attorneys

CIA - Corporate Integrity Agreement

CLIA - Clinical Laboratory Improvement Amendments

CMP - Civil Monetary Penalties

CMS - Department of Health and Human Services, Centers for Medicare & Medicaid Services

CMSO - Center for Medicaid and State Operations

CNA - Certified Nurse Aide

CRIPA - Civil Rights of Institutionalized Persons Act

DAB - Departmental Appeals Board

DME - Durable Medical Equipment

DOJ - The Department of Justice

DRG - Diagnosis Related Group

DSH - Disproportionate Share Hospital

DPAP - Division of Program Accountability and Payment

EKG - Transtelephonic Electrocardiogram

ESRD - End Stage Renal Disease

FBI - Federal Bureau of Investigation

FCA - False Claims Act

FDA - Food and Drug Administration

FEHBP - Federal Employees Health Benefits Program

FMDRP - Financial Management Data Redesign Project

GSK - GlaxoSmith Kline

GAO - General Accounting Office

HCFAC - -Health Care Fraud and Abuse Control Program

HHS - The Department of Health and Human Services

HI - Hospital Insurance Trust Fund

HIPAA, or the Act - The Health Insurance Portability and Accountability Act of 1996, P.L. 104-191

HMO - Health Maintenance Organization

IV - Intravenous

M+C - Medicare + Choice

MMA - Medicare Prescription Drug, Improvement and Modernization Act of 2003

MSN - Medicare Summary Notices

MSP - Medicare Secondary Payer

NHCAA - National Health Care Anti-Fraud Association

OGC - The Department of Health and Human Services, Office of the General Counsel

OIG - The Department of Health and Human Services, Office of Inspector General

OLE - Office of Legal Education, located within the Executive Office for the United States Attorneys

OPD - Outpatient Departments

PAM - Payment Accuracy Measurement

PERM - Program Error Rate Measurement

PPS - Prospective Payment System

The Program - The Health Care Fraud and Abuse Control Program

Secretary - The Secretary of the Department of Health and Human Services

SCHIP - State Children's Health Insurance Plan

SMP - Senior Medicare Patrol

TAG - Technical Advisory Group

TENS - Transcutaneous Electrical Nerve Stimulation

TIPS - Transactions, Information Inquiry, and Program Performance System

USAO - United States Attorney's Office

UPIN-Unique Physician Identity Number

WMSD - Waiver Management System Database